Office Action Summary	Application No.	Applicant(s)	
	10/576,589	LEATHWICK ET AL.	
	Examiner	Art Unit	
	AUDREA J. BUCKLEY	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 25-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/23/2010*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *Attached* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Acknowledgement is made of Applicant's claim amendments and remarks/arguments filed 7/6/2010.

Claims 1-21, and 25-28 are pending and under consideration herein.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 8/23/2010 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Withdrawn Claim Rejections

The rejection of claims 1, 2, 4-8, 10, 11, 14, 17, 19, and 21 under 35 U.S.C. 103(a) as being unpatentable over Forster et al. (AU 52162/96 A, filed May 1996, see IDS filed 4/21/2006) in view of Hennessy et al. (US 5,840,324, patented Nov. 1998) as evidenced by Lau et al. (WO 2004/069242 A1) is withdrawn in light of Applicants' amendments to the claims filed 7/6/10.

The rejection of claims 3, 9, 20, and 25 under 35 U.S.C. 103(a) as being unpatentable over Forster et al. (AU 52162/96 A, filed May 1996, see IDS filed 4/21/2006) in view of Hennessy et al. (US 5,840,324, patented Nov. 1998) as evidenced by Lau et al. (WO 2004/069242 A1) and further in view of Whitehead (US 6,030,637,

patented Feb. 2000) is withdrawn in light of Applicants' amendments to the claims filed 7/6/10.

The rejection of claim 12 under 35 U.S.C. 103(a) as being unpatentable over Forster et al. (AU 52162/96 A, filed May 1996, see IDS filed 4/21/2006) in view of Hennessy et al. (US 5,840,324, patented Nov. 1998) as evidenced by Lau et al. (WO 2004/069242 A1) and further in view of IVS Annual Index of Veterinary Products is withdrawn in light of Applicants' amendments to the claims filed 7/6/10.

The rejection of claims 15, 16, and 18 under 35 U.S.C. 103(a) as being unpatentable over Forster et al. (AU 52162/96 A, filed May 1996, see IDS filed 4/21/2006) in view of Hennessy et al. (US 5,840,324, patented Nov. 1998) as evidenced by Lau et al. (WO 2004/069242 A1) and further in view of Sanyal et al. is withdrawn in light of Applicants' amendments to the claims filed 7/6/10.

Maintained Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 15, and 16 provisionally are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 20 of copending Application No. 11908708. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the features of instant claim 1 are included in copending application claims 1-4 which outline a composition included in the instantly claimed method, although the copending application further limits the formulation components and expands the time period of active agent release. Likewise,

claims 15 and 16 of the instant invention are drawn to the same subject matter as claims 1 and 2 of the copending application, where the duration of active agent release is obvious in view of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

New Grounds of Rejection as Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 10, 11, 14-19, 21, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forster et al. (AU 52162/96 A, filed May 1996, see IDS filed 4/21/2006, previously cited) in view of Ludwig et al. (US 4,331,652, issued May 1982, newly cited) as evidenced by Lau et al. (WO 2004/069242 A1, previously cited).

Regarding claims 1, 2, 6-8, 10, and 26-28, Forster et al. teaches synergistic compositions of benzimidazoles (microtubule disruptors) and abamectin (a macrocyclic lactone that is a chloride channel blocker) as anthelmintics including nematocidal compositions. Benzimidazoles are generally microtubule disruptors, whereas

abamectin is a chloride channel blocker. Thus Forster clearly taught compositions comprising antihelmintics with different chemical groups and activities as required by claims 1 and 2, respectively. The formulation effectively targets ascarids, hookworms, whipworms, and heartworms upon the combination of abamectin (dosage between 5 and 15 ug per kg of animal body weight) and benzimidazole or pro-benzimidazole (dosage between 15 and 30 mg per kg of animal body weight) (see page 3, paragraph 3). As to claim 21, the first Example of the invention demonstrates a palatable tablet in chewable form as a delivery device (see page 4, paragraph 4). Similarly and further regarding claims 4-6, Lau et al. teach anthelmintic compositions comprising benimidazoles, macrocyclic lactones, and a therapeutically acceptable carrier wherein the formulation demonstrates "excellent control (>99.9% reduction) or a mixed gastrointestinal strongyle burden as assessed" (page 17, paragraph 1). That is, Lau evidences that the parasite burden on an animal necessarily would be controlled upon administration of the anthelmintic compositions.

Regarding claim 1, Forster et al. do not disclose an intra-ruminal bolus delivery device, a stepwise method, or efficacy duration.

Nonetheless, Ludwig et al. teach the controlled release of an anthelmintic agent from a bolus (see column 8, lines 48 - column 9, line 7) into the rumen of a ruminal animal (see column 7, line 56). Ludwig teaches that the parasiticide provides uniform protection against the parasites for a predetermined period of time (see column 2, lines 17-24) such as a time period of about 10 to about 60 days (see column 4, lines 13-15) but typically about 10 to 30 days. The payout periods were specifically monitored up to

14 days (see Table 1, column 8, lines 55-65). The bolus is to be administered orally (see column 7, line 55).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the bolus device and method of administering anthelmintic agents as taught by Ludwig et al. to administer the synergistic anthelmintic compositions of Forster et al. One would have been motivated to do so since Ludwig teaches that the advantages of the bolus device include the lack of undesired chemical residues in animals used for human food production as well as the advantage that the controlled release formulation does not expose the host animal to lethal doses of the active agent (see column 2, lines 8-20).

As to claims 3, 19, and 25, the active agent is administered by uniform controlled release (substantially continuous) (see Ludwig column 6, lines 32-36); it is noted that the instant specification does not provide a definition for a "substantially continuous rate". As to claim 11, Ludwig teaches albendazole as a particular benzimidazole used in Example 10 (see column 13, line 65). As to claim 14, Ludwig teaches sheep as a ruminant animal for which the disclosed dosage is suitable (see column 7, line 53). As to claims 15 and 16, Ludwig teaches that the bolus affords treatment to the animal for as long as about 10 to about 60 days, typically about 30 days (see column 6, lines 37-39). For a ten day treatment period, the active agents necessarily are released for a period of between 5 and 10 days as in claims 15 and 27 and a period of between 6 and 8 days as in claims 16 and 28. As to claims 17 and 18, Ludwig teaches the state of the art indicating that the imidazothiazoles known in the art effectively inhibit helminthiasis

(helminthes) (see column 3, line 35) and that the invention applies to ectoparasites such as lice, ticks, and fleas (see column 1, line 15).

Claims 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forster et al. (AU 52162/96 A, filed May 1996, see IDS filed 4/21/2006) in view of Ludwig et al. (US 4,331,652, issued May 1982, newly cited) as evidenced by Lau et al. (WO 2004/069242 A1) as applied above and further in view of Whitehead (US 6,030,637, patented Feb. 2000, previously cited).

The teachings of Forster et al. and Ludwig et al. are set forth above. Neither of these references explicitly teaches the dosage quantity as in claim 9 and maximum integral dose as in claim 20.

Nonetheless, Whitehead teaches a bolus of elements, each having a degradable outer sheath and a core of the active formulation (see column 2, line 18) for deposition of the active agents to a ruminant (see column 1, line 19; column 1, line 26). More specifically, Whitehead teaches the option of utilizing boli which release the active agent continuously as a function of time (see column 1, line 19). As to claim 9, Whitehead teaches an embodiment of the invention in which abamectin is used in a dose rate of 0.2 mg/kg, in combination with other anthelmintic active agents, for a formulation treating parasites in sheep (see page 36, Table 33: Treatment table, Group 2, dose rate). As to claim 20, Whitehead teaches an embodiment of the invention in which a bolus comprising a plurality of discrete bolus elements releases the biologically active material at different respective intervals based on the adapted sheath formulation (see

column 4, lines 22-30); further, the drug can be administered in integral units over a few hours to a period of a few months (see column 5, lines 1-10). Therefore, a formulation released in a pulse fashion necessarily has a maximum integral dose.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate the bolus-related teachings of Whitehead in order to formulate a controlled delivery device and dosage amount for the anthelmintic compositions of Forster et al. and Ludwig et al. One would have been motivated to do so in order to improve the efficacy of the formulation by controlling the delivery so as to increase dosage or decrease dosage as a function of delivery time as taught by Whitehead. Likewise, one would have been motivated to look to the quantity of anthelmintically effective active agents in the formulation of Whitehead since these formulations combine active agents for a variety of animal sizes including sheep.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Forster et al. (AU 52162/96 A, filed May 1996, see IDS filed 4/21/2006) in view of Ludwig et al. (US 4,331,652, issued May 1982, newly cited) as evidenced by Lau et al. (WO 2004/069242 A1) as applied above and further in view of IVS Annual Index of Veterinary Products (see IDS, 5/31/2007).

The teachings of Forster et al. Lau et al., and Ludwig et al. are delineated above. None of these references teaches the particular dosage of albendazole as in pending claim 12.

However, the IVS Annual Index teaches that 4.75 mg/kg of albendazole is an effective dosage quantity for rendering anti-parasitic effects in sheep.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize the dosage quantity of albendazole as taught by the IVS Annual Index in the formulations of Forster et al. and Ludwig et al. One would have been motivated to do so in order to impart the known benefits of such a dosage while expecting to minimize harmful side effects of an overdose, particularly since the skilled artisan would have considered the IVS Annual Index a reference source for dosage details associated with known active agents such as anti-parasites, and, more specifically, albendazole.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Forster et al. (AU 52162/96 A, filed May 1996, see IDS filed 4/21/2006) in view of Ludwig et al. (US 4,331,652, issued May 1982, newly cited) as evidenced by Lau et al. (WO 2004/069242 A1) as applied above, and further in view of Sanyal et al. (Vet. Res. Comm. *20*, 1996, 461-468).

The teachings of Forester and Lau et al., and Ludwig et al. are delineated above. None of these references teaches the particular anthelmintic compound that is tricalbendazole.

However, Sanyal et al. teach that tricalbendazole is an effective low-level intraruminal anti-fluke anti-parasite agent (see abstract, in particular).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute tricalbendazole as the anthelmintic agent as taught by Sanyal et al. into the formulations of Forester and Ludwig which also utilize known anthelmintic active agents. One would have been motivated to do so in order to impart the known anti-parasite effects of tricalbendazole as well as its ability to bind to albumin better than nematocidial benzimidazoles such as oxfendazole or fenbendazole (see page 465, Discussion, paragraph 1).

Response to Arguments

Applicant's arguments presented 7/6/2010 have been fully considered but are moot in light of the new grounds of rejection set forth above. As noted above, all rejections previously presented and not re-iterated herein are withdrawn. Applicant's positions against cited references are summarized and responded to as follows.

Applicants take the position that the previously cited references fail to teach the bolus "configured to release from the rumen" (see page 6 of remarks of 7/6/10). Applicant takes the position that the Hennessy reference is inappropriate because it teaches the use of finely dispersed particles which are designed to pass into the abomasum and small intestine and not the rumen (last paragraph, page 6 of remarks and end of first paragraph, page 7 of remarks). Applicant's position has been considered but is moot in light of the new grounds of rejection.

Applicant takes the position that the cited art (namely, Hennessy) teaches away from the instantly recited method. Applicant's argument is not persuasive but is otherwise moot in light of the new grounds of rejection.

Applicant presents that the claimed method meets a long-felt unmet need (page 8 of remarks). Applicant's position has been considered, but this secondary consideration is not persuasive in view of the obviousness rejection newly presented herein.

Applicant's remaining arguments all relate to the Hennessy reference which is no longer relied upon as necessitated by amendments to the claims. Therefore, these arguments are unpersuasive. Applicant does not at this time rebut the double patenting rejection of record; therefore, the double patenting rejection is maintained as presented above.

Conclusion

No claims are found allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA J. BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AJB/

/Richard Schnizer/
Primary Examiner, Art Unit 1635